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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,883

09/07/2006

Mark Denison

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EXAMINER

KINSEY WHITE, NICOLE ERIN

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

12/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,883	Applicant(s) DENISON, MARK	
	Examiner NICOLE KINSEY WHITE	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 16-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-15 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/5/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of Group I (claims 2-5 and 10-11) in the reply filed on August 20, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The abstract of the disclosure is objected to because it is incomplete as filed. Correction is required. See MPEP § 608.01(b).

Status of Claims

Claims 1-40 are pending, and claims 5-8 and 16-35 are withdrawn from further consideration as not being drawn to the elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonilla et al. (Virology. 1995; 209: 489-497).

The claims are drawn to a live, attenuated virus of the order *Nidovirales*, said virus characterized as comprising a genome encoding a replicase polyprotein with at least one cleavage site that exhibits reduced or no cleavage.

Bonilla et al. discloses a murine hepatitis virus that contains a deletion at cleavage sites p28-p65. The virus of Bonilla et al. exhibits reduced or no cleavage at the cleavage site (see the abstract, Table 1 and Figure 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonilla et al. (Virology. 1995; 209: 489-497) and further in view of Van Dinten et al. (Journal of Virology. 1999; 73 (3): 21027- 2037) and Bryaas et al. (US 3,590,127).

The claims are drawn to vaccine formulations.

The teachings of Bonilla et al. are outlined above. Bonilla et al. does not teach a vaccine for inducing an immune response.

Van Dinten et al. teaches mutagenesis at multiple cleavage sites of a virus in the order *Nidovirales* that abolished protein processing and resulted in inhibition of infectious virus production, see the abstract and Figures 2-6.

Bryans et al. teaches a method of inducing an immune response with a vaccine produced from a virus in the order *Nidovirales* that is attenuated by serial passage, see claims 1-4.

One of ordinary skill in the art at the time the invention was made would have been motivated to administer the deletion mutant viruses of Bonilla et al. to induce an immune response against the virus, see column 2, lines 5-28 of Bryans et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of inducing an immune response with the deletion mutant of Bonilla et al. because Van Dinten et al. teaches analogous deletion mutations that negatively effect protein cleavage that reduces the capacity to produce infectious progeny, see the last paragraph on page 2036, and Bryans et al. demonstrates that avirulent viruses comprising multiple mutations induce protective immune responses, see column 3, line 39 to column 5, line 21. Alternatively, one of ordinary skill in the art at the time the invention was made would have been motivated to recombinantly incorporate the mutations of Van Dinten et al. or Bonilla et al. into the virus vaccine of Bryans et al. to reduce the possibility of wild-type reversion. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for introducing the corresponding proteinase deletions of Bonilla et al. or Van Dinten et al. into the virus of Bryans et al. (or any other virus in the order *Nidovirales*) because Van Dinten et al. and Bryans et al. both teach attenuating measures for viruses.

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With regard to claims 37-40, it is well within the purview of one of ordinary skill in the art to vary the dose or non-essential components or storage conditions of the vaccine.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Nicole Kinsey White/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648